ULLMAN, SHAPIRO & ULLMAN, LLP

COUNSELORS AT LAW
299 BROADWAY, SUITE 1700
NEW YORK, NY 10007
TEL. (212) 571-0068
FAX. (212) 571-9424
USU@USULAW.COM

ROBERT ULLMAN
STEVEN SHAPIRO*
MARC S. ULLMAN

ELIZABETH S.
GIOIOSA DILLABOUGH †

OF COUNSEL:
MILTON A. BASS
IRVING L. WIESEN

*ADMITTED IN N.Y. & N.J.
†ADMITTED IN D.C., MA., & ONTARIO, CANADA ONLY

TRADEMARK COUNSEL:
DENNIS H. CAVANAUGH
274 MADISON AVE.
SUITE 300
NEW YORK, NY 10016

WASHINGTON AFFILIATE
James M. Johnstone
1776 K STREET, N.W. -THIRD FL.
WASHINGTON, D.C. 20006

LONDON AFFILIATES
Wedlake Bell
16 BEDFORD STREET
COVENT GARDEN
LONDON WC2E 9HF
ENGLAND

E.U. CORRESPONDENT
Lafili, Van Crombrugghe
& Partners
VOSSENDREEF 6 BUS 1
B-1180 BRUSSELS
BELGIUM

COMMENTS OF MARC S. ULLMAN, ESQ. ON BEHALF OF TRACO LABS, INC. AT THE FDA PUBLIC MEETING CONCERNING IMPLEMENTATION OF PEARSON V. SHALALA AND THE VIABILITY OF HEALTH CLAIMS CONCERNING EFFECTS ON EXISTING DISEASES

Good afternoon, my name is Marc Ullman. I am a partner in the New York City law firm Ullman, Shapiro & Ullman, LLP. I appear here today on behalf of Traco Labs, Inc., a manufacturer and supplier of dietary supplements based in Champaign, Illinois. Over the past 10 years, Traco has consistently urged FDA to permit the free flow of all truthful and nonmisleading information concerning the important health benefits of dietary supplements. This position has been grounded in the notion that only with this complete information may American consumers take full control over matters related to their health, and make fully informed, intelligent decisions on this all important issue. Once again today, Traco appears here to urge the FDA to allow the free flow of truthful and nonmisleading information to consumers by taking all steps necessary to implement the D.C. Circuit Court's decision in Pearson v. Shalala, and by acknowledging that health claims which discuss effects on existing disease conditions are permissible under the Federal Food, Drug and Cosmetic Act.

In the Federal Register Notice announcing this meeting, FDA requested that comments address a series of questions the Agency posed pertaining to these issues. I will attempt to

00D-0338

T58

address the most pertinent of these in the brief amount of time allotted for this presentation at the end of this long day.

Implementation of the Pearson Decision

1. What is the best regulatory approach for public health?

Traco firmly believes that the answer to this question is one which allows for the free flow of truthful and nonmisleading information. The public health is best served when consumers are provided with truthful information relating to the broad range of health benefits that can be provided by dietary supplements. Moreover, our First Amendment jurisprudence repeatedly has expressed a preference for disclosure rather than suppression of information. Thus, in its 1977 ruling in Bates v. State Bar of Arizona the Supreme Court noted that "We view as dubious any justification that is based on the benefits of public ignorance." Similarly, in his 1996 opinion for the plurality in 44 Liquormart v. Rhode Island, Justice Stevens recognized that "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for their own good."

Of equal import, however, Traco believes that there is no place in the market for misleading, false information. Such information is entitled to no First Amendment protection, and the full array of FDA's enforcement powers are properly utilized against those individuals and companies marketing products on the basis of such misinformation.

2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence?

Traco believes that the answer to this question is an unqualified yes. Such

qualifications can be clearly presented in a manner that alerts the consumer to the actual state of current scientific belief without causing undue confusion. Several examples of such disclaimers were cited by the D.C. Circuit in the Pearson decision. To the extent that FDA has expressed concern that certain disclaimers and qualifying language may be so broad as to justify even the most outrageous claims, Traco respectfully submits that the Pearson decision does not require the Agency to validate any and all claims so long as they are accompanied by a disclaimer. It is well established in our case law that false promotional claims may not be protected by over-arching disclaimers. What Pearson does require, however, is that FDA explain the basis for its decision in rejecting a claim, rather than simply announcing that it has failed to pass some unarticulated standard.

To the extent that the Agency has sought information from the supplement industry demonstrating that disclaimers and qualifying language can be used in conjunction with certain health claims without causing consumer confusion, Traco respectfully notes that the Pearson Court expressly recognized that ***the burden is on FDA*** to justify any restriction it may seek to place on speech, and that it is not the industry's burden to justify the speech. Specifically, the Court stated that "Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech."

HEALTH CLAIMS AND EXISTING DISEASE CONDITIONS

The second major area on which the Agency has sought input concerns whether claims of effects on existing diseases or conditions are permissible as health claims. Traco believes that the answer to this is an unqualified yes.

In the March 16 Federal Register announcing this forum, FDA suggests that various nuances contained in the interrelationship between the statutory definitions of food, drug and medical food indicate that Congress intended that authorized health claims be limited to claims relating to reduction of the risk of disease. Thus, the Agency postulates that "if Congress had intended to permit any kind of disease claim for foods, it could have exempted all foods bearing authorized health claims from the drug definition in section 210(g) of the Act which provides that 'an article intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease' is a drug."

This reasoning is flawed in several important respects. First, it fails to recognize that a product may be deemed a drug by virtue of things other than claims made on its behalf. For example, it may contain an ingredient which was the subject of an IND or approved NDA prior to its introduction into the marketplace as a food. This tension between drug and food is currently the subject of litigation relating to red rice yeast extracts.

Second, this portion of the FDCA states that the product shall not be considered a drug by virtue of the use of an approved health claim. The presence of other, unauthorized claims may still render the product a drug. If Congress had utilized language such as suggested by the Agency in the Federal Register notice, this might not be the case.

Finally, and perhaps most importantly, FDA's approach ignores the plain language of the statute. Congress has authorized the use of health claims characterizing the relationship between a nutrient and a disease or health related condition. Nothing in this portion of the statute indicates any Congressional intent to limit health claims solely to disease prevention. If this is what Congress had intended, it simply could have allowed health claims characterizing the relationship between a nutrient and the reduction of the risk of disease or health related

conditions. It did not do this. Instead, the plain language of the FDCA currently contains no such limitation, and Traco respectfully submits that an interpretation by the Agency to the contrary would be without justification or legal basis.